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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,734	01/25/2002	A. Robert Spitzer	0594.00034	9911

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EXAMINER

BERKO, RETFORD O

ART UNIT PAPER NUMBER

1615

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/056,734	Applicant(s) SPITZER, A. ROBERT	
	Examiner Retford Berko	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22,25,27 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22,25,27 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement: Applicant's Amendment filed January 13, 2004 is acknowledged.

Status of Claims

1. The status of the claims is as follows:
 - (a) Claims 1-21, 28, 29, 31 and 32 are withdrawn from consideration in view of applicant's amendment.
 - (b) Claims 23, 24 and 26 are cancelled in view of applicant's amendment.
 - (c) Claims 22, 25, 27 and 30 are pending.
2. The texts of the Sections of Title 35 U.S.C. used in the previous office action are not included in this office action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

 - a. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in that the claim refers to "valproate salts and valproate variations thereof", making it unclear as to the metes and bounds of the invention. Also, Claim 23 is rejected under Sec. 112 second paragraph because the use of the term "valproate variations" lacks antecedent basis. Applicant may overcome the rejection by clarifying what valproate variations means.
 - b. In regards to claim 24, the phrase "ergotamine-like agents" renders the claim indefinite because it is an improper Markush group and it is unclear what specific compounds fall into the group. Applicant may overcome the rejection by naming specific compound in the group.

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c. In regards to Claim 24, the term “5HT agonists” renders the claim indefinite because 5HT is not readily discernable or understood in the art. Applicant may overcome the rejection by specifying what biochemical entity or what activity is regulated by the compounds referred to as “agonists” in the claim.

2. Claim 30 is rejected under 35 U.S.C. Sec 112, first paragraph, because the specification, while being enabling for the administration of effective amount of the valproate and its salts as suppository, does not reasonably provide enablement for the use of any medicament composition into the rectum of an individual for treating migraine headache. The specification does not enable any person skilled in the art, to which it pertains, or with which it is most nearly connected, to use all medicaments in the form as suppository to treat migraines as commensurate in scope of the claim.

Claim Rejections-Sec. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 22-25, 27 and 30 are rejected under 35 U.S.C. 102 (b) as anticipated by prior art taught by Baker et al (US 6, 071, 927) and by Crocker et al (US6, 096, 742). Applicant's claims are drawn to a suppository composition including valproate, aspirin, naproxen, acetaminophen, ibuprofen, serotonin agonists, thickeners, solvents and preservatives for treatment of migraines.

3. Baker et al taught an invention that treatment or prevention of pain, inflammation, migraine and emesis could be achieved by rectal administration of a composition comprising

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effective amounts of acetaminophen, aspirin, ibuprofen and naproxen and valproate (abstract, col 8, lin 48, col 14, lin 15-25 and col. 21, lin 30-35). *Thus, applicant's invention in Claims 22-25 and 27 and 30 was taught by the invention patented by Baker et al. Therefore, applicant is precluded from obtaining a patent for invention described in claims 22-25, 27 and 30; consistent with the requirements of Sec. 102(b).*

4. Crocker et al taught an invention wherein headache, migraine and pain were treated by administration of a composition comprising acetaminophen, aspirin, ibuprofen, naproxen and valproate (col 10, lin 65; col 12, lin 50-55). The reference also teaches that the composition may be used in the form of a pharmaceutical preparation in solid, semisolid or liquid form; that the active ingredient may be compounded with pharmaceutically acceptable carriers for tablets, capsules and suppositories in addition, auxiliary thickening and coloring agents. Furthermore, the prior art taught that isopropyl acetate was used as the solvent (col 14, lin 31-50). The teachings in Crocker et al are implicit to a person skilled in the art to invent a composition as claimed by applicant because the composition as a suppository will constitute an effective delivery of the medication for treatment of migraine as taught by the prior art. Therefore, applicant is precluded from obtaining a patent for the invention described in claims 22-25, 27 and 30; consistent with Sec. 102(a).

Rejection Withdrawn

3. Rejections of claims 22-25, 27, and 30 as anticipated by prior art taught by Baker et al (US 6, 071, 927 and by Crocker et al (US 6, 096, 742) are withdrawn in view of the amendments to the claims.

Response To Arguments

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4. Applicant's arguments filed January 13, 2004 have been fully considered but they are found not persuasive.

5. Claim 22, 25, 27 and 30 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims do not define the metes and bounds of the medicament used for rectal administration.

6. Claims 22-25, 27 and 30 remain rejected under 35 U.S.C. 102 (b) as anticipated by Baker et al (US 6, 071, 927) and Crocker et al (US 6, 096, 742).

7. Applicant argues that neither Patent '927 nor Patent '742 disclose a composition only including valproate, sodium valproate, and/or valproate salts; contending that as distinct from the instant claimed invention, that both Patent '927 and Patent '742 disclose a composition including additional components such as acetaminophen, aspirin, ibuprofen and naproxen.

8. In response to the above argument, the examiner reads the meaning of the patent disclosure as permitting optionally additional drugs to be included in the formulation (col 21, lin 5-35; also specification at page 5, lin 12-28). Therefore the reference teaches a single drug.

9. Applicant argues that because claim 22 has been amended and is currently drawn toward a medicine suppository composition selected from the group consisting of valproate, sodium valproate, and valproate salts and because claim 30 has also been amended and is currently drawn toward a method of treating a migraine headache; that the presently claimed invention is patentably distinct over the cited prior art references.

10. In response to this argument, it is the examiner's position that as the examiner reads the specification as filed to permit additional drugs to be included in the composition consistent with the prior art teaching in Patent '927 and Patent '742 as indicated above. Also, Patent '742 teaches the use of the composition in suppositories (col 14, lin 35-40).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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